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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,061	06/26/2001	Nicholas R. Bachur JR.	P-5026	1747
26253	7590	10/07/2003	EXAMINER	
BECTON, DICKINSON AND COMPANY			BEISNER, WILLIAM H	
1 BECTON DRIVE			ART UNIT	PAPER NUMBER
FRANKLIN LAKES, NJ 07417-1880			1744	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,061	BACHUR ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-58 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-58 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 January 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 7, 9, 10, 20, 23, 24, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakahara et al.(US 3,807,876).

With respect to claims 1 and 20, the reference of Nakahara et al. discloses a device and method of use for monitoring the concentration of a gas in at least one container (10). The device includes an energy emitting device (20, 24) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (column 3, line 67, to column 4, line 37). The device includes a detector (36) and a signal analyzer (40) to determine the concentration of the gas and/or whether the gas exists in the container.

With respect to claims 4 and 24, the signal analyzer of the primary reference is determining an absorption by the targeted gas.

With respect to claims 7 and 23, the reference discloses the detection of SO₂ and the wavelength band required for the detection of SO₂ (See column 4, lines 8-10).

With respect to claims 9 and 28, the wavelength bands employed are considered infrared light (See column 1, lines 7-30).

With respect to claims 10 and 29, the system includes a spectrograph device (See column 4, line 60, to column 5, line 14).

3. Claims 1, 3, 4, 5, 9, 10, 11, 13, 15, 18, 19, 20, 22, 24, 25, 28, 29, 30, 32, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Brace (US 5,614,718).

With respect to claims 1 and 20, the reference of Brace discloses a device and method of use for monitoring the concentration or pressure of a gas (carbon dioxide) in at least one container (20). The device includes an energy emitting device (62) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 5, lines 23-64). The device includes a detector (63) and a signal analyzer (54) to determine the concentration or pressure of the gas and/or whether the gas exists in the container.

With respect to claims 5, 11, 25 and 30, the reference discloses that the absorption data can be used to determine pressure or change in pressure within the container (See column 5, lines 8-25).

With respect to claims 3, 13, 22 and 32, the reference of Brace is employing a wavelength band to determine concentration of carbon dioxide within the container.

With respect to claims 4, 15, 24 and 34, the signal analyzer of the primary reference is determining an absorption by the targeted gas.

With respect to claims 9, 18, 28 and 37, the wavelength bands employed are considered infrared light (emitting device 62).

With respect to claims 10, 19, 29 and 38, the system includes a spectrograph device (54).

4. Claims 1, 3, 4, 6, 9, 10, 20, 22, 24, 26, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Perks et al.(EP 0151855).

With respect to claims 1 and 20, the reference of Perks et al. discloses a device and method of use for monitoring the concentration of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See page 11, lines 13-18). The device includes a detector (17) and a signal analyzer (See page 13, lines 19-28 and Figure 7) to determine the concentration of the gas and/or whether the gas exists in the container.

With respect to claims 3 and 22, the reference of Perks et al. is employing a wavelength band to determine concentration of carbon dioxide within the container (See page 11, lines 13-18).

With respect to claims 4 and 24, the signal analyzer of the primary reference is determining an absorption by the targeted gas.

With respect to claims 6 and 26, the reference is identifying the presence of microorganisms within the container.

With respect to claims 9 and 28, the wavelength bands employed are considered infrared light (emitting device 15).

With respect to claims 10 and 29, the system includes a spectrograph device (See page 13, lines 19-28, and Figure 7)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 7, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Fraatz et al.(EP 0448923) and Nakahara et al.(US 3,807,876).

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The reference of Perks et al. has been discussed above.

The above claims differ by reciting that other gas components other than carbon dioxide are detected by the detection system.

The reference of Fraatz et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See page 3, lines 31-24).

The reference of Nakahara et al. discloses that it is known in the art to detect individual or simultaneously a number of different components within a gas mixture using IR spectrometry (See columns 1 and 2).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel.

9. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Kruezer (US 3,700,890).

The reference of Perks et al. has been discussed above.

While the reference of Perks et al. discloses the use of an IR light source, the instant claims differ by reciting the use of a laser light source.

The reference of Kruezer discloses that it is known in the art of gas spectroscopy to employ laser light source (See column 4, lines 41-51).

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In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a laser light source for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a desired wavelength band of liquid for gas component detection.

10. Claims 39-41 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Carr et al.(US 5,888,825).

The reference of Perks et al. has been discussed above.

While the system of Perks et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation

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environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

11. Claims 51, 52, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Berndt et al.(US 5,518,923).

The reference of Perks et al. has been discussed above.

While the system of Perks et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

12. Claims 5, 11, 13, 15, 18, 19, 25, 30, 32, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The reference of Perks et al. has been discussed above.

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The above claims differ by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

13. Claims 12, 14, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Waters (US 4,952,498), Brace (US 5,614,718), Fraatz et al.(EP 0448923) and Nakahara et al.(US 3,807,876).

The combination of the references of Perks et al. with Waters and Brace has been discussed above.

The above claims differ by reciting that other gas components other than carbon dioxide are detected by the detection system.

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The reference of Fraatz et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See page 3, lines 31-24).

The reference of Nakahara et al. discloses that it is known in the art to detect individual or simultaneously a number of different components within a gas mixture using IR spectrometry (See columns 1 and 2).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel.

14. Claims 17 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Waters (US 4,952,498), Brace (US 5,614,718) and Kruezer (US 3,700,890).

The combination of the references of Perks et al. with Waters and Brace has been discussed above.

While the reference of Perks et al. discloses the use of an IR light source, the instant claims differ by reciting the use of a laser light source.

The reference of Kruezer discloses that it is known in the art of gas spectroscopy to employ laser light source (See column 4, lines 41-51).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention

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was made to employ a laser light source for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a desired wavelength band of liquid for gas component detection.

15. Claims 42-44 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Waters (US 4,952,498), Brace (US 5,614,718) and Carr et al.(US 5,888,825).

The combination of the references of Perks et al. with Waters and Brace has been discussed above.

While the system of Perks et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation

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environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

16. Claims 53, 54, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perks et al.(EP 0151855) in view of Berndt et al.(US 5,518,923).

The combination of the references of Perks et al. with Waters and Brace has been discussed above.

While the system of Perks et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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The reference of Nix et al.(US 5,473,161) is cited as a prior art reference that pertains to the detection of carbon dioxide gas within a sealed container using IR spectrometry.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB